REMARKS

The present application was filed on September 27, 2001 having claims 1-27. Claims 1-19 have been withdrawn from consideration. Claims 20 and 24 have been amended herein, and claim 21 has been cancelled, so claims 20 and 22-27 remain pending in the application.

In the Office Action dated May 21, 2003, the Examiner: (1) rejected claims 22 and 24 under 35 U.S.C. §112, second paragraph as being indefinite; (2) rejected claim 24 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,959,068 to Bendel et al.; (3) rejected claim 20 under 35 U.S.C. §103(a) as obvious over Bendel et al. in view of U.S. Patent No. 5,928,268 to Butwell et al.; (4) rejected claims 20, 22, 24, and 26 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,025,025 to Bartrug et al. in view of U.S. Patent No. 5,258,013 to Granger et al; and (5) rejected claims 21, 23, 25, and 27 under 35 U.S.C. §103(a) as obvious over Bartrug et al. in view of Granger et al.

With respect to the rejection of claims 22 and 24, applicants respectfully traverse the rejection under 35 U.S.C. § 112, second paragraph. According to the Examiner, claim 22's recitation "the silicone-containing coating comprises an interpenetrating network" is indefinite and is not supported in the specification. Contrary to the Examiner's assertion, the specification describes a coating mixture for a needle which includes a polydialkylsiloxane and a siliconization material that does not covalently bond with the polydialkylsiloxane. "Once the mixture is formed, it can then be applied to the surface of a surgical needle . . . . The coating mixture is then subjected to curing conditions, e.g., the curing steps discussed above, such that the siliconization material polymerizes and cross-links thereby interlocking the polydimethylsiloxane in the coating resulting in an interpenetrating networked coating." Specification at p. 14. Clearly, the specification supports the limitation that the silicone-containing coating comprises an interpenetrating network; moreover, the specification clearly defines what is meant by such a network – the components of the silicone coating are not covalently bound to each other but instead one component cross-links thereby interlocking the other component in the coating.

According to the Examiner, claim 24's recitation "whereby the surgical needle has a penetration force on a fifth pass through tissue" is indefinite because it is unclear what type of tissue is being used to measure the needle's penetration force. See Office Action at page 2. While not agreeing with the Examiner's assertion, applicants have amended claim 24 herein to recite the reduced penetration force on a fifth pass through "a microporous polyurethane member of about 0.042 inches thickness" which was the material tested in the Examples (commercially available as Porvair from Inmont Corporation).

The Examiner next rejected claim 24 under 35 U.S.C. §102(b) in view of Bendel et al. According to the Examiner,

> Bendel et al. disclose a surgical needle having a reduced penetration force comprising a surgical needle having an acid-treated surface . . . and a silicone-containing coating on at least a portion of the acid treated surface. . . . The surgical needle is capable of having a penetration force on a fifth pass through a tissue of a needle having the same silicone-containing coating but that is not acid treated. The needle's surface is activated by an acid, which helps the silicone coating bind to the surface (see U.S. Patent No. 6,025,025: col. 2, ll. 66-67; col. 3, ll. 1-11).

(*See* Office Action at pages2-3.)

However, nowhere does Bendel et al. disclose or suggest needles having "a penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness that is at least 10% less than the penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness of a needle having the same silicone-containing coating on the same surgical needle having no surface that is acid treated" as required by amended claim 24. Bendel et al. is simply not concerned with improving penetration forces by pre-treating a needle.

To the contrary, the purpose of the acid treatment in Bendel et al. is not to improve penetration force, but rather to blacken the needle to form a dark, non-reflective,

non-flaking surface having improved visibility in the surgical field. While the examples of Bendel et al. report penetration characteristics, in view of the vastly different purpose of the Bendel et al. treatment, it is not surprising that Bendel et al. does not disclose that its acid treatment results in reduced penetration forces after multiple passes through a microporous polyurethane member of about 0.042 inches thickness. Bendel et al. is merely concerned with improving visibility of the needle. Bendel et al. does not address improving penetration force or even appreciate that maintaining good penetration force after multiple passes through tissue is a concern. Accordingly, independent claim 24 is believed to be patentably distinct from the Bendel et al. patent. Therefore, in view of the above remarks, reconsideration of this rejection is respectfully requested.

Claim 20 was rejected under 35 U.S.C. §103(a) as obvious over Bendel et al. in view of Butwell et al. Nowhere does Bendel et al. disclose or suggest that an aminoalkyl siloxane may be utilized to form a silicone coating on an acid treated needle as presently required by amended Claim 20. As described above, Bendel et al.'s acid treatment was not to enhance adherence of a coating to its needle, but rather to blacken the needle to form a dark, non-reflective, non-flaking surface having improved visibility in the surgical field. While Bendel et al. states its needles may be lubricated with a silicone, there is no mention of the use of aminoalkyl siloxane as required by amended claim 20.

Butwell et al. fails to remedy the deficiencies of Bendel et al. Like Bendel et al., Butwell et al. fails to disclose or suggest coating its surgical needles with a silicone comprising an aminoalkyl siloxane as required by amended claim 20. Nor is there any disclosure or suggestion in Butwell et al. of treating its needles with acid. Thus, neither Bendel et al. nor Butwell et al., taken alone or in any combination, render amended claim 20 obvious.

Claims 20, 22, 24 and 26 were rejected under 35 U.S.C. §103(a) as obvious over Bartrug et al. in view of Granger et al.

Bartrug et al. fails to disclose anything about surgical needles. Thus Bartrug et al. fails to disclose acid treatment of a surgical needle surface. Bartrug et al. also fails to disclose improving needle penetration forces after five passes through tissue.

It is not surprising that Bartrug et al. discloses nothing with respect to surgical

needle penetration forces since Bartrug et al. is directed to methods for improving the adherence of water-repellent films on the surface of a substrate. While Bartrug et al. discloses a wide variety of substrates which may be coated, only glass substrates are exemplified. In fact, as admitted by the Examiner, Bartrug et al. does not disclose treating needles, and there is nothing in Bartrug et al. to suggest its compositions may be utilized to improve the lubricity of surgical needles.

Moreover, Bartrug et al. teaches away from Applicants' acid treatment. According to Bartrug et al. at Col. 3, Lines 11-24,

> The abrading compound/acid solution dispersion loosens and dislodges materials, such as surface contaminants and other glass constituents, which block the bonding sites, without materially affecting the mechanical or optical properties of the surface of the substrate. A synergistic effect has been observed where the abrading compound is dispersed in the acid solution. More particularly, a water-repellent film applied to a substrate surface prepared with the abrading compound/acid solution dispersion generally exhibits improved durability as compared to preparing the substrate surface with an abrading operation alone or an acid washing operation alone, and at least as good or better than an abrading operation followed [sic] a separate acid washing operation.

One reviewing Bartrug et al.'s abrading compound/acid solution dispersion to obtain enhanced water-repellency for glass would in no way be motivated to attempt such a treatment on a surgical needle to obtain enhanced lubricity. In fact, the abrasive compound of Bartrug et al. may very well degrade the needles to an extent rendering them unfit for medical use. In addition, the synergy of abrading compound and acid solution as described by Bartrug et al. would suggest to one skilled in the art that an acid treatment alone is insufficient to obtain a water-repellent coating and similarly would be insufficient for the treatment of needles as disclosed by applicants.

Granger et al. discloses a needle that is coated with silicone. However, in order to establish the *prima facie* obviousness of a claim, "there must be some suggestion or

motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." *See* MPEP §2143. Nowhere is there any suggestion or motivation to combine Bartrug et al. and Granger et al. in the manner suggested in the Office Action.

One skilled in the art faced with the problem of improving needle penetration force would not, in the first instance, look to Bartrug et al.'s abrading compound/acid solution for enhanced water repellency, especially since glass is the only substrate exemplified by Bartrug et al. Nor would one skilled in the art have any motivation to combine Bartrug et al.'s teachings with respect to water repellency on glass with Granger et al.'s silicone-coated needle. Without such suggestion or motivation, independent Claims 20 and 24 are non-obvious over Bartrug et al. and Granger et al. whether taken alone or in any combination. Claims 22 and 26, which depend from Claims 20 and 24 respectively, are thus non-obvious over the references as they incorporate all of the limitations of their dependent base claims.

Claims 21, 23, 25 and 27 were also rejected under 35 U.S.C. §103(a) as unpatentable over Bartrug et al. in view of Granger et al. Claim 21 has been cancelled herein, thus rendering the rejection of Claim 21 moot. Claim 23 depends from Claim 20 and Claims 25 and 27 depend from Claim 24. As Claims 20 and 24 are non-obvious for the reasons described above, Claims 23, 25 and 27 incorporate all of the limitations of their dependent base claims and thus are also non-obvious over Bartrug et al. and Granger et al. no matter how the references are combined.

It is believed that the claims of the application as now presented, i.e., claims 20 and 22-27, are patentably distinct over the art of record and are in condition for allowance. In the event that the examiner believes that a telephone conference or a personal interview may facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. In view of the foregoing amendment and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,

Peter DeLuca
Reg. No. 32,978
Attorney for Applicants

CARTER, DELUCA, FARRELL & SCHMIDT, LLP
445 Broad Hollow Road - Suite 225
Melville, New York 11747
(631) 501-5700
(631) 501-3526 (fax)
PD/MRB/jjc